Cognitive Rehabilitation with Mobile Technology and Social Support for Veterans with TBI and PTSD: A Randomized Clinical Trial

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Abstract

Objective: To investigate effects of cognitive rehabilitation with mobile technology and social support on veterans with traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD).

Participants: 112 dyads comprised of a veteran and family member or friend (224 participants total).

Design: Dyads were randomized to: 1) a novel intervention, Cognitive Applications for Life Management (CALM), involving goal management training plus mobile devices for cueing and training attentional control, or 2) Brain Health Training, involving psychoeducation plus mobile devices to train visual memory.

Main Measures: Executive dysfunction (disinhibition, impulsivity) and emotional dysregulation (anger, maladaptive interpersonal behaviors) collected prior to randomization and following intervention completion at six months.

Results: The clinical trial yielded negative findings regarding executive dysfunction but positive findings on measures of emotion dysregulation. Veterans randomized to CALM reported a 25% decrease in anger over six months compared to 8% reduction in the control (B=-5.27, p=.008). Family/friends reported veterans randomized to CALM engaged in 26% fewer maladaptive interpersonal behaviors (e.g., aggression) over six months compared to 6% reduction in the control (B =-2.08, p=.016). An unanticipated result was clinically meaningful change in PTSD symptoms among veterans randomized to CALM (p<.001).

Conclusion: This preliminary study demonstrated effectiveness of CALM for reducing emotional dysregulation in veterans with TBI and PTSD.

Key words: traumatic brain injury; posttraumatic stress disorder; veterans; cognitive rehabilitation; mobile technology; social support; executive function; emotion regulation.

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Traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD) frequently co-occur in military veterans[1-3] and it is estimated that up to 50% of veterans with TBI meet criteria for PTSD.[3,4] Brain areas affected by TBI are also implicated in PTSD, particularly those encompassing executive functions critical for emotional and behavioral regulation.[2,5,6] Comorbid TBI and PTSD in veterans has been linked to reduced inhibitory control,[4,6] difficulties with affect regulation,[4,5] problems with anger and violence[7,8] and poorer social function.[9] Despite this, we are unaware of interventions targeting these adverse outcomes within this at-risk subgroup of veterans.

Shallice's theory of the Supervisory Attentional System (SAS) conceptualizes executive function as involving separate processes of inhibition, attention, self-monitoring, and planning.[10,11] Gordon et al.[12] propose that these processes along with emotion regulation should be key components of a theory-based cognitive rehabilitation of executive dysfunction. Scholarship on rehabilitation of executive function thus supports use of multimodal approaches to optimize improving outcomes.[11,12]

From this framework, "metacognitive" strategies have been implemented to improve self-monitoring, emotion regulation, and self-control.[13-15] One such intervention, goal management training (GMT), helps individuals learn strategies to set personal goals, break complex tasks into steps, and monitor attention in order to gain cognitive control and reorient behaviors to be goals-consistent.[16,17] GMT has led to improvements in emotional regulation[18] and social functioning in TBI,[19] especially when integrated with "content-free cues" (e.g., unsystematic prompts) designed to remind individuals to practice goal-directed behavior in real life settings.[18]

Additionally, attention training has been employed to address other facets of executive function. In this regard, the n-back task has been used to directly train individuals to increase attentional control, inhibition, and working memory.[20] This task involves conscious and deliberate use of strategies to effectively allocate attentional resources to improve working memory and inhibitory control, both which are linked to improved social and occupational functioning.[21,22] Attention training has been shown to be effective, including when used in combination with metacognitive training.[15,23,24]

Finally, cognitive rehabilitation strategies can be enhanced in the context of social support[25] and by use of mobile health technology, which extend treatment from the clinic to home settings.[26] Research has shown social support plays a critical role in community reintegration of veterans with TBI[27] and PTSD[28] and demonstrates protective effects on outcomes such as aggression and violence in veterans.[29]

Empirical literature supports use of cognitive rehabilitation for improving executive function and emotion regulation, most commonly in TBI[23] but also PTSD.[14] This article describes a randomized clinical trial testing the effects of a cognitive rehabilitation intervention called Cognitive Applications for Life Management (CALM) on executive function and emotion regulation in veterans with TBI and PTSD. Designed in accordance with the conceptual framework and empirical literature on rehabilitation of executive function described above, CALM combines GMT, content-free cueing, and the n-back task, delivers these via a mobile device, and involves support of a family member or friend. In this preliminary study, we hypothesized that veterans in the CALM intervention group would show greater reduction on measures of disinhibition, impulsivity, emotional dysregulation, and maladaptive behaviors compared to veterans in an active control group at six-month follow-up.

Method

Participants

After approval by the Institutional Review Board at a university medical center, participants were recruited through veterans' health facilities and organizations in the Southeastern Region of the United States. Inclusion criteria included veterans being between ages of 18 and 65, serving in the military after October 2001, having a trusted family member or friend consent to participate, and meeting TBI and PTSD criteria. For TBI, veterans needed to meet Department of Defense/Department of Veterans Affairs (DoD/VA) criteria of having incurred an injury to the head as a result of blunt trauma, acceleration or deceleration forces, or exposure to blast that resulted in one or more of the following: skull fracture; brain surgery; any period of observed or self-reported transient confusion, disorientation, or altered/impaired consciousness; dysfunction of memory immediately after the time of injury; or loss of consciousness.[30] For PTSD, veterans needed to meet Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria using the Clinician-Administered Posttraumatic Stress Disorder Scale (CAPS).[31] This study was designed to randomize 100 veteran-family/friend dyads evenly to experimental and active control groups, thus providing 80% power to detect effect sizes equivalent to Cohen's $d = 0.57$.

Procedure

Data collection occurred from January 2012 to February 2016. Veterans selected a trusted family member or friend to serve as a support person for the study. At our research offices, veterans and family/friends provided written informed consent. Veterans were then evaluated by interview for TBI and PTSD by a post-doctoral or master's level clinician under supervision of a licensed psychiatrist and psychologist.

After, veterans completed assessment and self-report measures. Family/friends completed questionnaires about veterans' TBI-related behaviors. Veterans and family/friends were each compensated for participation. Following the 6-month intervention period, the assessment was administered again to veterans and family/friend who were compensated for participation. Interviewers collecting study data were blind to participants' study condition for both baseline and 6-month follow-up assessments.

Intervention

Following the baseline interview, veteran-family/friend dyads were randomized to an experimental or active control group. Both conditions lasted six months and involved three 60-90 minute home visits at 0, 2, and 4 months with the veteran and support person by a clinical facilitator in order to conduct the intervention, promote treatment engagement, and troubleshoot technology issues. In both conditions, veterans were provided an iPod Touch configured to leave only functions necessary for the study (following study completion, functions were unlocked and the device was given to the participant). In both conditions, a family member/friend: 1) attended home visits and received the same educational materials as did veterans; and 2) were instructed to provide support and encourage veterans to engage in their respective interventions.

Veteran-family/friend dyads in the experimental group received Cognitive Applications for Life Management (CALM), comprised of several components. Initially, clinical facilitators provided GMT educational materials and didactic exercises[17,18] to teach veterans how to become alert to a specific goal, define it, list and learn the steps involved, and monitor feedback after task execution. Veterans designed behavioral checklists for a self-chosen two-month GMT goal (e.g., pay utility bills on time, spend more time with child, lose five pounds), then broke goals down into steps, utilizing

applications on mobile devices to record steps and set reminders on the iPod calendar application to complete GMT goal actions. At each subsequent home visit, a new two-month goal would be set by the veteran. A mobile application called "Mind Jogger" provides similar technology to past research providing "content free cues"[18,19] by randomly prompting (four times a day during waking hours) an "Executive Review," which involved veterans themselves asking the following *in vivo*: "What am I doing? What is my goal? What steps do I need to enact to achieve that goal? Do I need to refocus my concentration to enact these steps?" Veterans were asked to use a mobile application called "IQ Boost" daily to conduct the n-back task, in which they were presented a sequence of visual and/or auditory stimuli and then asked to identify whether the current stimulus was the same as the n^{th} prior stimulus. The n-back exercise lasted a few minutes and veterans were encouraged but not required to do multiple exercises at one sitting.

Veteran-family/friend dyads in the active control group received psychoeducation on TBI and used mobile devices to train visual memory. Clinical facilitators provided didactics and reviewed "Brain Health Training" psychoeducational materials about TBI and brain functioning, used previously in control groups in studies of GMT.[17,18] Additionally, veterans were asked to daily use a mobile application called "Unotan Memory" that involves matching colors, numbers, and images with visual-memory exercises. As in the experimental group, each exercise lasted a few minutes and veterans were encouraged but not required to do multiple exercises at one sitting.

Clinical facilitators were observed by other project staff using fidelity checklists until they achieved greater than 85% fidelity for six participant dyads (three in each study group). Afterward, facilitators could conduct sessions independently and then were observed randomly every three months to assure continued protocol fidelity.

Measures

Executive function was measured by the Delis-Kaplan Executive Function System (DKEFS) Color-Word inhibition task, a well-validated cognitive test measuring ability to inhibit automatic responses,[32] and the Barratt Impulsiveness Scale (BIS),[33] a self-report measure of attention, motor impulsivity, self-control, and cognitive instability.

Emotional regulation was measured by the Dimensions of Anger Reactions (DAR),[34] a self-report measure of anger disposition directed toward other people designed for and validated in combat veterans with PTSD, and the Head Injury Behavior Scale (HIBS),[35] a 20-item scale administered to family/friends to rate maladaptive interpersonal behaviors in individuals with head injuries (e.g., aggression, poor decision-making, irritability, lack of initiative).

Number of home visits completed (out of a possible 3) were measured. Application usage could not be directly captured by the mobile device and after use of an application, participants pressed a single button to log usage on an application called "Event Logger." Veterans and family/friends in the CALM group were asked whether veterans achieved GMT goals.

We administered the 17-item CAPS to measure frequency and intensity of PTSD symptoms.[31] Clinically meaningful change in PTSD symptoms is defined as a change in CAPS scores by 10 or more points.[36]

Statistical Analysis

Statistical analyses were conducted using SAS version 9.4. Descriptive analyses were conducted on characteristics of veterans and intervention process. To test hypotheses, difference scores for each outcome variable were tabulated by subtracting pretreatment scores from posttreatment scores. Then, difference scores were regressed

on treatment group, controlling for centered baseline levels of the outcome variable. Two sets of regression models were analyzed for each outcome. The first used listwise deletion (LD) and thus only included participants with baseline and posttreatment data. The second used an intent-to-treat (ITT) approach with last observations carried forward for participants with missing posttreatment data. Given PTSD was an inclusion criteria, we ran exploratory regression models of change in CAPS scores by treatment condition.

Results

Figure 1 presents the CONSORT diagram of participant flow through the study procedures. At randomization, the sample consisted of 112 Veteran-Family/Friend dyads. Social support included spouses/significant others (71%), friends (11%), parents (10%), siblings (2%), and "other" (6%). With respect to getting together with the family member/friend in the past year, 17% of veterans (n =19) reported at least once a day; another 23% (n = 25) at least once per week; 22% (n = 24) at least once per month; 27% (n = 30) less than once a month; and 11% (n = 12) not at all. With respect to talking on the telephone with the family member/friend in the past year, 32% of veterans (n =35) reported least at least once a day; another 35% (n = 39) at least once per week; 25% (n = 28) at least once per month; 6% (n = 7) less than once a month; and 2% (n = 2) not at all.

Of the 112 veteran/family-friend dyads (N=224 participants total), 89 returned at six months and provided posttreatment data (n = 41 in the CALM group and n = 48 in the Control group). Age, gender, CAPS, number of TBI, and racial status were not significantly associated with missing data. A greater percentage of CALM participants (28%) were missing posttreatment data than control participants (13%), $X^2(1) = 4.04$, p = .045. Background characteristics of veterans are reported in Table 1.

Across both study conditions, participants completed a mean of 2.73 out of 3 possible home visits (*SD* = 0.54). Visit rate did not vary by treatment condition, (*t*(87) = 0.77, *p* = .45). Not finishing all three home visits was mainly due to scheduling conflicts. Over the 6-month study, participants in CALM self-logged conducting an executive review after being cued a mean of 188.60 times (*SD* = 202.20) and using the n-back application a mean of 73.05 times (*SD* = 84.15). Participants in the control group self-logged using the visual-memory application a mean of 90.77 times (*SD* = 57.27). During the CALM intervention, 66% (n = 25) reported completing at least one GMT goal which generally involved physical, spiritual, financial, environmental, occupational, emotional/mental, intellectual, or social domains of wellness. Goal success in the CALM group was significantly associated with number of home visits conducted by clinical facilitators with veteran-family/friend dyads (*r* (36) = .44, *p* = .005).

Main hypotheses using regression analyses of treatment-related changes are reported in Table 2. No statistically significant changes by group on the DKEFS Color-Word inhibition task or the BIS were detected. However, significant treatment effects were observed for anger and TBI-related behavioral issues. Using an LD approach, veterans randomized to CALM reported an average 7.89-point decrease in anger towards others over six months on the DAR compared to 2.62 reduction in veterans in the control group (*B*= -5.27, *p* = .008) (see Figure 2). This difference on the DAR was significant (*B*= -3.35, *p* = .038) using an ITT approach. Family/friends reported that veterans randomized to CALM engaged in 2.39 fewer maladaptive interpersonal behaviors on the HIBS over six months on average, significantly greater than the reduction of 0.31 among veterans in the control (*B*= -2.08, *p* = .016). Group differences on the HIBS were significant using an ITT approach (*B*= -1.58, *p* = .021).

Pre- and posttreatment means and regression models of CAPS total, frequency, and intensity scores are listed in Table 3. Whereas the control group experienced a mean decrease in total symptom severity by 8.37 points (p = .002), the CALM group experienced a mean decrease of 15.20 points (p < .001). There was a trend for a treatment effect on total PTSD symptom severity when LD was used (B=-6.84, p = .084). Treatment effects were not significant in the ITT model and there were no significant effects on PTSD symptom intensity. However, in the PTSD symptom frequency model using the LD approach, treatment effects were significant (B=-4.09, p = .047), indicating veterans in the CALM group experienced greater decreases in symptom frequency than veterans in the control group.

Discussion

In the current study, veterans randomized to the CALM group did not show greater improvements in executive function but did demonstrate significantly larger decreases in anger towards others compared with veterans in the control group. Family/friends also reported significantly larger decreases in veterans randomized to the CALM group engaging in maladaptive behaviors such as aggression, irritability, and poor decision-making compared with those in the control group. Of CALM components, veterans' successful achievement of GMT goals was related to number of home visits by clinical facilitators. An unexpected result was that the CALM intervention was significantly associated with decreased PTSD symptoms.

Regarding executive function, we did not detect group differences in changes on the DKEFS Color-Word inhibition task or BIS. One possibility is that perhaps a different combination of training tasks would have yielded more favorable results on these particular outcomes. Another explanation is that only 12% of our sample demonstrated

functioning in the borderline or impaired range on the DKEFS color-word inhibition task at baseline, denoting a ceiling effect regarding ability to improve scores. Because most participants scored below the commonly used cut-off of 74 for impulsivity problems on the BIS,[33] our ability to assess reduction in impulsivity may likewise be due to floor effects. This has implications for clinical trials; namely, TBI alone may be insufficient as inclusion criteria for future treatment studies, which should instead specify cognitive and/or behavioral criteria.

Regarding emotional and behavioral regulation, current findings are consistent with research in cognitive rehabilitation of TBI showing that metacognitive strategies targeting self-awareness of beliefs, self-monitoring, and self-control are effective at improving social functioning.[13,18,19,23] That CALM was associated with greater reduction in anger toward others is noteworthy in treatment of veterans. In a nationally representative survey of U.S. Veterans,[37] 61.2% reported experiencing difficulties controlling anger while 23.9% reported experiencing aggressive urges over a two-year period. However, treatment of anger in veterans has lagged behind treatment of anxiety/fear and randomized clinical trials of anger treatments for veterans are rare.[7,38] CALM differs from most anger management interventions because it does not explicitly require identifying anger as a target, though it may encourage mindfulness and awareness of anger through random content free-cueing. Our results suggest integrating cognitive rehabilitation strategies into more targeted anger management programs for veterans may have potential for improving clinical and functional outcomes.

An unanticipated result was that over six months, total CAPS scores decreased by more than 15 points in veterans randomized to the CALM group, representing a clinically meaningful change in PTSD symptoms, defined as change in CAPS scores by 10 or more

points.[36] In hindsight, this might have been anticipated by the framework of psychosocial rehabilitation which posits that self-determination and self-direction are central tenets of recovery.[29] Further, given PTSD is a disorder characterized by feeling out of control of internal and external events,[39] it is not unreasonable to infer that providing tools and opportunities to practice strategies to achieve personally relevant goals could result in greater sense of control and reduction in PTSD symptomatology.

That the current study extends benefits of cognitive rehabilitation to veterans with TBI *and* PTSD is important because cognitive rehabilitation is seldom used in treating PTSD,[14] even though PTSD is linked to neuropsychological deficits.[3,4,40] The finding that CALM improved PTSD symptoms challenges the notion cognitive rehabilitation should be reserved for TBI only. The data imply PTSD and TBI should not necessarily be treated as distinct, non-overlapping conditions in veteran populations but instead be treated concurrently. The results support use of cognitive rehabilitation in conjunction with psychotherapeutic practices for veterans with PTSD.

Study limitations should be considered. The data may not generalize to all veterans with co-occurring TBI and PTSD because some veterans may not have a family member or friend they trust to participate in treatment. It is unknown whether CALM would yield similar effects for TBI-only or PTSD-only, though the fact that we observed improvement in an arguably more impaired population[2,4] speaks to potential for benefit. Similarly, future work could examine effects of CALM in civilian populations with TBI and/or PTSD.

Because mobile devices could not be programmed to measure application use, participants' self-logged entry served as a proxy. Although precise usage is unknown, participants in CALM automatically received content-free cues regardless of whether this

was logged in. Future studies should investigate optimal dosage, incorporate objective use measures, and track performance on the applications themselves. Given research on veterans with TBI and PTSD, we elected to study anger and impulsivity; however there are other domains of emotion regulation (e.g., coping skills) that warrant future study.

Although inclusion of family/friend informant data of TBI-related maladaptive behaviors is a strength of the study, the same informants were involved in administration of the interventions; ideally, future research would include collateral reports by individuals not involved in the intervention. Also, while we took steps to assure equivalence between study conditions regarding amount of time spent with clinical facilitators, it is possible the CALM group (e.g., involving goal setting) asked for somewhat more active effort on the part of participants than the control group (e.g., involving psychoeducation), which could be one reason more dyads dropped out of the former than the latter. Finally, longer term follow-up data would be useful to determine durability and longevity of effects of CALM.

On a practical level, the study identified that provision of a mobile device to facilitate cognitive rehabilitation was feasible. Its availability for use may have served as an incentive for initial participation in the study and encouraged ongoing participation throughout the study. The CALM intervention lends itself to the possibility of integrating it into treatment, involving social support, potentially using telemedicine and telerehabilitation to accomplish home visits, or developing it as an entirely self-directed application.

Still, that goal achievement was related to number of home visits challenges the notion of self-administered mobile technology and shows the contribution of clinician facilitation. Moreover, it will be important to study use of CALM in naturalistic settings

where individuals may use it on their smart phone devices which have other applications unrelated to cognitive rehabilitation. Additionally, attention should be given to understanding under which conditions social support facilitated improvement in CALM. More generally, the mechanism of change in CALM still needs investigation to determine whether benefits resulted from GMT goals, content-free cueing, the n-back, number of home visits, engagement of social support in veterans' recovery process, or an integrated face-to-face and technological treatment package. Future dismantling studies would help identify mechanisms of observed effects.

The results of this randomized clinical trial of the CALM intervention suggest that a mobile-based cognitive rehabilitation intervention is a viable approach to use with veterans and a family member or friend, and that it can result in improvements in emotional and behavioral regulation in veterans with co-occurring TBI and PTSD. Although this study is a preliminary step and findings need to be replicated, the results indicate that CALM holds promise for treating a growing population of veterans faced with what have become the two signature injuries of the wars in Iraq and Afghanistan.

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Table 1.

Baseline Participant Characteristics

	All (N = 112)	Control (n = 55)	CALM (n = 57)	p
Age	36.52 (8.42)	36.25 (8.30)	36.77 (8.60)	.75
Sex (female)	11 (10%)	5 (10%)	4 (10%)	.92
Racial minority status	53 (47%)	24 (50%)	14 (34%)	.13
TBI count	2.63 (1.24)	2.62 (1.25)	2.64 (1.24)	.92
TBI moderate/severe	64 (57%)	29 (53%)	35 (61%)	.35
CAPS total	75.63 (17.30)	75.98 (18.06)	75.30 (16.68)	.84
CW total	9.31 (3.51)	8.81 (3.68)	9.79 (3.32)	.15
BIS total	71.29 (12.75)	71.31 (12.42)	71.26 (13.17)	.98
DAR total	30.72 (15.55)	31.11 (15.54)	30.35 (15.69)	.80
HIBS total	8.72 (5.31)	9.80 (5.56)	7.68 (4.89)	.04

Note. Means/frequencies and standard deviations/percentages (in parentheses). CALM = Cognitive Applications for Life Management; TBI = traumatic brain injury; CAPS = Clinician Administered Posttraumatic Stress Disorder Scale; CW = DKEFS Color-Word inhibition task; BIS = Barratt Impulsivity Scale; DAR = Dimensions of Anger; HIBS = Head Injury Behavior Scale

Table 2.

Unadjusted Mean Changes and Modeled Unstardardized Treatment Effects on Changes in Main Outcome Variables

		Means (Standard Deviations)				Regression Coefficients (Standard Errors)		
		CALM		Control				
Outcome	Model	Pre	Post	Pre	Post	Intercept	Baseline level	Treatment[a]
Executive Function/Impulsivity								
CW	LD	9.80 (3.50)	10.25 (3.36)	8.69 (3.79)	9.91 (3.24)	0.76* (0.31)	-0.25** (0.06)	-0.12 (0.44)
	ITT	9.79 (3.32)	10.18 (3.23)	8.85 (3.68)	9.53 (3.48)	0.58* (0.25)	-0.18** (0.05)	-0.10 (0.35)
BIS	LD	69.34 (12.84)	67.29 (11.72)	71.04 (12.81)	68.98 (11.80)	-2.11* (0.98)	-0.21** (0.06)	-0.35 (1.44)
	ITT	71.26 (13.17)	69.79 (12.66)	71.31 (12.42)	69.69 (12.64)	-1.61† (0.83)	-0.14** (0.05)	0.14 (1.17)
Emotion/Behavior Regulation								
DAR	LD	30.68 (15.57)	22.80 (16.53)	30.74 (16.15)	28.13 (15.39)	-2.62* (1.31)	-0.17** (0.06)	-5.27** (1.93)
	ITT	30.35 (15.77)	24.82 (16.53)	31.13 (16.15)	28.85 (15.56)	-2.22† (1.14)	-0.14** (0.05)	-3.35* (1.60)
HIBS	LD	7.68 (4.88)	5.66 (4.67)	9.33 (5.21)	8.81 (5.23)	-0.31 (0.58)	-0.35** (0.09)	-2.08* (0.84)
	ITT	7.68 (4.89)	6.23 (4.83)	9.80 (5.56)	9.44 (5.77)	-0.12 (0.47)	-0.23** (0.06)	-1.58* (0.67)

Note. Negative effects reflect decreases in outcome measures from pre- to posttreatment; positive effects reflect increases. CALM = Cognitive Applications for Life Management; CW = DKEFS Color-Word inhibition task; BIS = Barratt Impulsivity Scale; DAR = Dimensions of Anger; HIBS = Head Injury Behavior Scale; LD = listwise deletion; ITT = intent to treat. †$p < .10$, *$p < .05$, **$p < .01$

[a] CALM vs. Control

Table 3.

Unadjusted Mean Changes and Modeled Unstandardized Treatment Effects on Changes in Exploratory PTSD Variables

CAPS Outcome	Model	Means (Standard Deviations)				Regression Coefficients (Standard Errors)		
		CALM		Control				
		Pre	Post	Pre	Post	Intercept	Baseline level	Treatment[a]
Total	LD	74.88 (16.85)	60.33 (25.14)	76.54 (18.07)	67.64 (24.05)	-8.34** (2.65)	-0.04 (0.11)	-6.84† (3.91)
	ITT	75.30 (16.68)	64.63 (23.92)	75.98 (18.06)	68.82 (23.55)	-7.15** (2.27)	-0.03 (0.09)	-3.53 (3.19)
Frequency	LD	38.98 (9.45)	29.80 (12.99)	39.71 (10.25)	34.02 (12.99)	-5.43** (1.37)	-0.08 (0.10)	-4.09* (2.02)
	ITT	39.42 (9.11)	32.75 (12.67)	39.64 (10.32)	35.00 (12.93)	-4.63** (1.21)	-0.05 (0.09)	-2.04 (1.69)
Intensity	LD	35.90 (8.06)	30.53 (13.15)	36.83 (8.39)	33.62 (11.75)	-2.92* (1.46)	-0.09 (0.13)	-2.77 (2.16)
	ITT	35.88 (8.30)	32.75 (12.67)	36.35 (8.33)	35.00 (12.93)	-2.51* (1.22)	-0.08 (0.10)	-1.51 (1.71)

Note. Negative effects reflect decreases in outcome measures from pre- to posttreatment; positive effects reflect increases. CAPS = Clinician Administered Posttraumatic Stress Disorder Scale; CALM = Cognitive Applications for Life Management; LD = listwise deletion; ITT = intent to treat. †$p < .10$, *$p < .05$, **$p < .01$

[a] CALM vs. Control

Figure 1.

Study Procedures, Screening, and Participant Enrollment

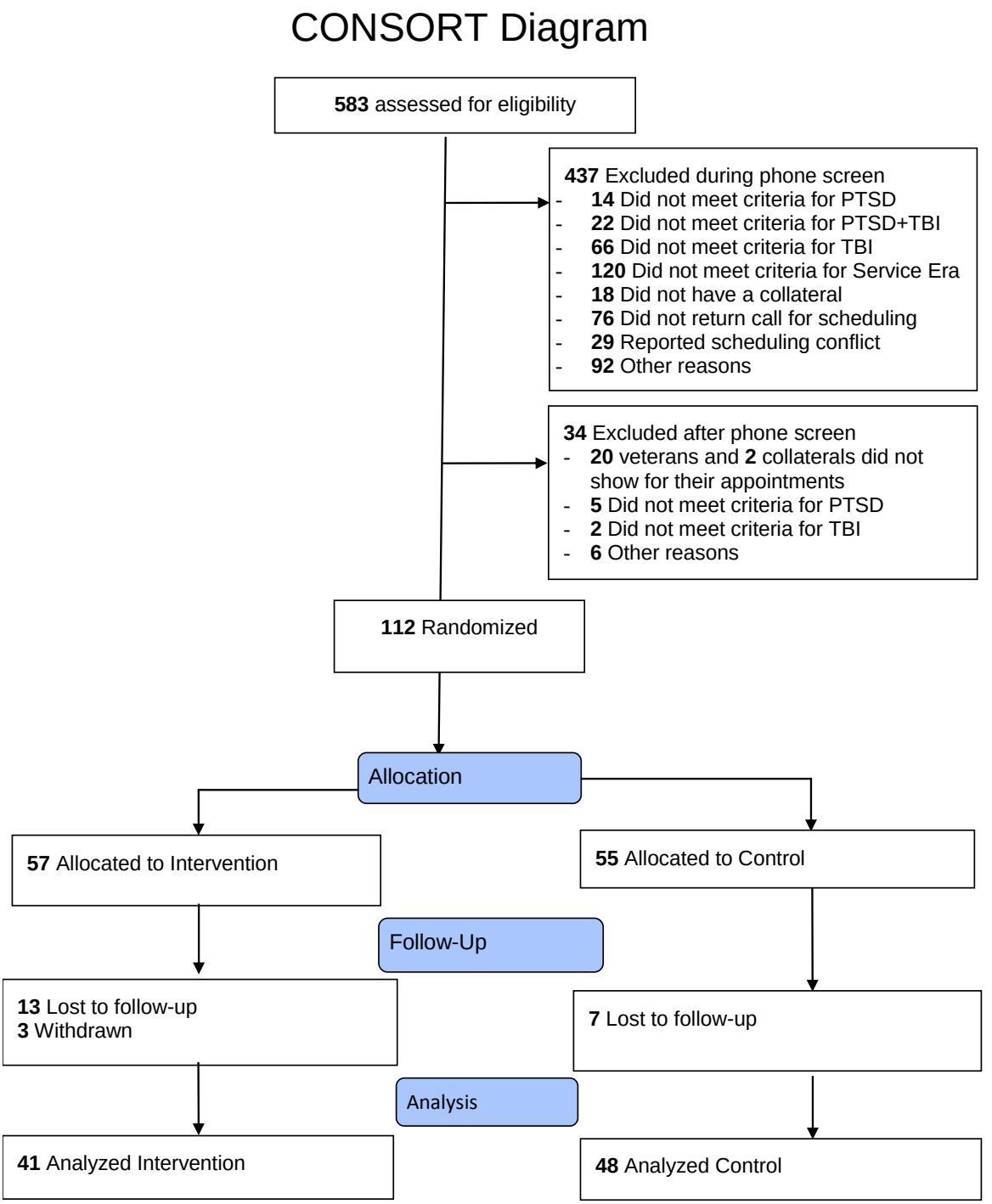
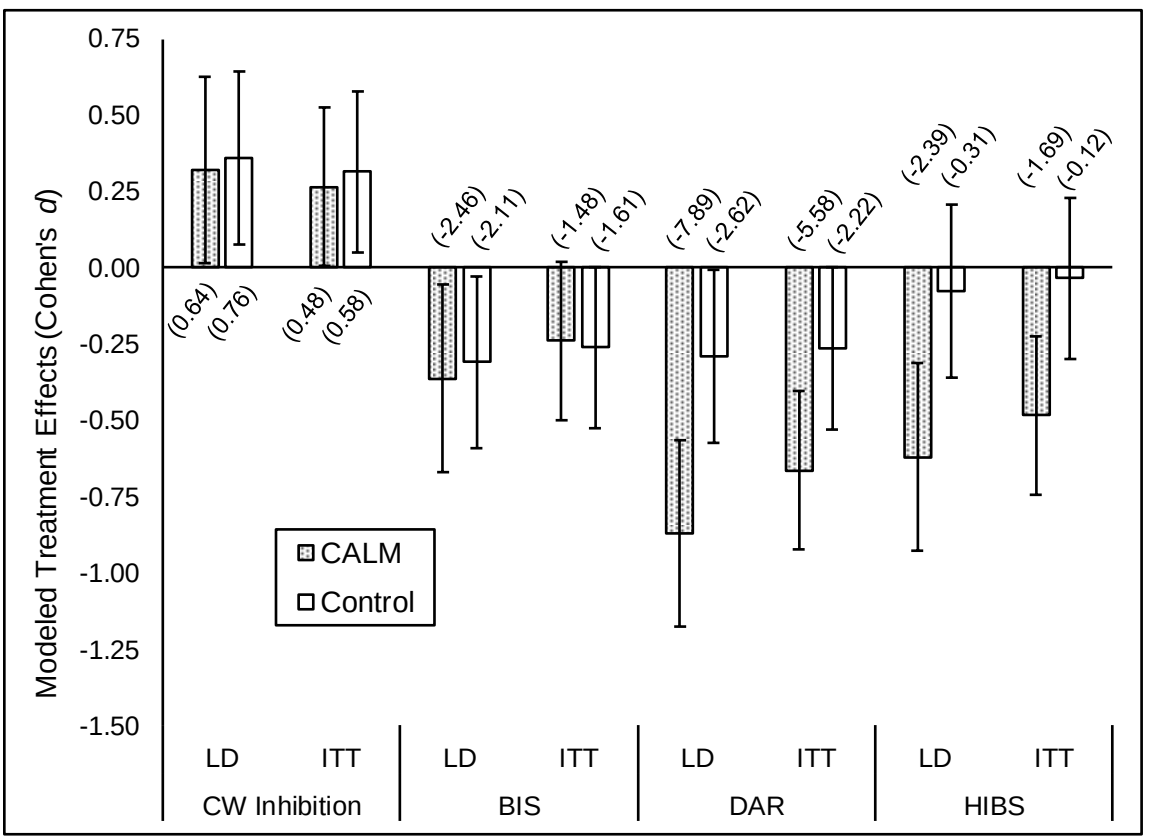


Figure 2.

Modeled treatment-associated changes in main outcome variables.



Note. Negative scores reflect reductions from baseline, positive scores increases. Standardized units (Cohen's *d*) are depicted with raw modeled change scores reported in parentheses. Error bars represent 95% confidence intervals. CALM = Cognitive Applications for Life Management; CW = DKEFS Color-Word inhibition task; BIS = Barratt Impulsivity Scale; DAR = Dimensions of Anger; HIBS = Head Injury Behavior Scale; LD = listwise deletion; ITT = intent to treat.

Unmasked Manuscript

Cognitive Rehabilitation with Mobile Technology and Social Support for Veterans with TBI and PTSD: A Randomized Clinical Trial

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Abstract

Objective: To investigate effects of cognitive rehabilitation with mobile technology and social support on veterans with traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD).

Participants: 112 dyads comprised of a veteran and family member or friend (224 participants total).

Design: Dyads were randomized to: 1) a novel intervention, Cognitive Applications for Life Management (CALM), involving goal management training plus mobile devices for cueing and training attentional control, or 2) Brain Health Training, involving psychoeducation plus mobile devices to train visual memory.

Main Measures: Executive dysfunction (disinhibition, impulsivity) and emotional dysregulation (anger, maladaptive interpersonal behaviors) collected prior to randomization and following intervention completion at six months.

Results: The clinical trial yielded negative findings regarding executive dysfunction but positive findings on measures of emotion dysregulation. Veterans randomized to CALM reported a 25% decrease in anger over six months compared to 8% reduction in the control (B=-5.27, p=.008). Family/friends reported veterans randomized to CALM engaged in 26% fewer maladaptive interpersonal behaviors (e.g., aggression) over six months compared to 6% reduction in the control (B =-2.08, p=.016). An unanticipated result was clinically meaningful change in PTSD symptoms among veterans randomized to CALM (p<.001).

Conclusion: This preliminary study demonstrated effectiveness of CALM for reducing emotional dysregulation in veterans with TBI and PTSD.

Key words: traumatic brain injury; posttraumatic stress disorder; veterans; cognitive rehabilitation; mobile technology; social support; executive function; emotion regulation.

Cognitive Rehabilitation with Mobile Technology and Social Support for Veterans with TBI and PTSD: A Randomized Clinical Trial

Traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD) frequently co-occur in military veterans[1-3] and it is estimated that up to 50% of veterans with TBI meet criteria for PTSD.[3,4] Brain areas affected by TBI are also implicated in PTSD, particularly those encompassing executive functions critical for emotional and behavioral regulation.[2,5,6] Comorbid TBI and PTSD in veterans has been linked to reduced inhibitory control,[4,6] difficulties with affect regulation,[4,5] problems with anger and violence[7,8] and poorer social function.[9] Despite this, we are unaware of interventions targeting these adverse outcomes within this at-risk subgroup of veterans.

Shallice's theory of the Supervisory Attentional System (SAS) conceptualizes executive function as involving separate processes of inhibition, attention, self-monitoring, and planning.[10,11] Gordon et al.[12] propose that these processes along with emotion regulation should be key components of a theory-based cognitive rehabilitation of executive dysfunction. Scholarship on rehabilitation of executive function thus supports use of multimodal approaches to optimize improving outcomes.[11,12]

From this framework, "metacognitive" strategies have been implemented to improve self-monitoring, emotion regulation, and self-control.[13-15] One such intervention, goal management training (GMT), helps individuals learn strategies to set personal goals, break complex tasks into steps, and monitor attention in order to gain cognitive control and reorient behaviors to be goals-consistent.[16,17] GMT has led to improvements in emotional regulation[18] and social functioning in TBI,[19] especially when integrated with "content-free cues" (e.g., unsystematic prompts) designed to remind individuals to practice goal-directed behavior in real life settings.[18]

Additionally, attention training has been employed to address other facets of executive function. In this regard, the n-back task has been used to directly train individuals to increase attentional control, inhibition, and working memory.[20] This task involves conscious and deliberate use of strategies to effectively allocate attentional resources to improve working memory and inhibitory control, both which are linked to improved social and occupational functioning.[21,22] Attention training has been shown to be effective, including when used in combination with metacognitive training.[15,23,24]

Finally, cognitive rehabilitation strategies can be enhanced in the context of social support[25] and by use of mobile health technology, which extend treatment from the clinic to home settings.[26] Research has shown social support plays a critical role in community reintegration of veterans with TBI[27] and PTSD[28] and demonstrates protective effects on outcomes such as aggression and violence in veterans.[29]

Empirical literature supports use of cognitive rehabilitation for improving executive function and emotion regulation, most commonly in TBI[23] but also PTSD.[14] This article describes a randomized clinical trial testing the effects of a cognitive rehabilitation intervention called Cognitive Applications for Life Management (CALM) on executive function and emotion regulation in veterans with TBI and PTSD. Designed in accordance with the conceptual framework and empirical literature on rehabilitation of executive function described above, CALM combines GMT, content-free cueing, and the n-back task, delivers these via a mobile device, and involves support of a family member or friend. In this preliminary study, we hypothesized that veterans in the CALM intervention group would show greater reduction on measures of disinhibition, impulsivity, emotional dysregulation, and maladaptive behaviors compared to veterans in an active control group at six-month follow-up.

Method

Participants

After approval by the Institutional Review Board at a university medical center, participants were recruited through veterans' health facilities and organizations in the Southeastern Region of the United States. Inclusion criteria included veterans being between ages of 18 and 65, serving in the military after October 2001, having a trusted family member or friend consent to participate, and meeting TBI and PTSD criteria. For TBI, veterans needed to meet Department of Defense/Department of Veterans Affairs (DoD/VA) criteria of having incurred an injury to the head as a result of blunt trauma, acceleration or deceleration forces, or exposure to blast that resulted in one or more of the following: skull fracture; brain surgery; any period of observed or self-reported transient confusion, disorientation, or altered/impaired consciousness; dysfunction of memory immediately after the time of injury; or loss of consciousness.[30] For PTSD, veterans needed to meet Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria using the Clinician-Administered Posttraumatic Stress Disorder Scale (CAPS).[31] This study was designed to randomize 100 veteran-family/friend dyads evenly to experimental and active control groups, thus providing 80% power to detect effect sizes equivalent to Cohen's $d = 0.57$.

Procedure

Data collection occurred from January 2012 to February 2016. Veterans selected a trusted family member or friend to serve as a support person for the study. At our research offices, veterans and family/friends provided written informed consent. Veterans were then evaluated by interview for TBI and PTSD by a post-doctoral or master's level clinician under supervision of a licensed psychiatrist and psychologist.

After, veterans completed assessment and self-report measures. Family/friends completed questionnaires about veterans' TBI-related behaviors. Veterans and family/friends were each compensated for participation. Following the 6-month intervention period, the assessment was administered again to veterans and family/friend who were compensated for participation. Interviewers collecting study data were blind to participants' study condition for both baseline and 6-month follow-up assessments.

Intervention

Following the baseline interview, veteran-family/friend dyads were randomized to an experimental or active control group. Both conditions lasted six months and involved three 60-90 minute home visits at 0, 2, and 4 months with the veteran and support person by a clinical facilitator in order to conduct the intervention, promote treatment engagement, and troubleshoot technology issues. In both conditions, veterans were provided an iPod Touch configured to leave only functions necessary for the study (following study completion, functions were unlocked and the device was given to the participant). In both conditions, a family member/friend: 1) attended home visits and received the same educational materials as did veterans; and 2) were instructed to provide support and encourage veterans to engage in their respective interventions.

Veteran-family/friend dyads in the experimental group received Cognitive Applications for Life Management (CALM), comprised of several components. Initially, clinical facilitators provided GMT educational materials and didactic exercises[17,18] to teach veterans how to become alert to a specific goal, define it, list and learn the steps involved, and monitor feedback after task execution. Veterans designed behavioral checklists for a self-chosen two-month GMT goal (e.g., pay utility bills on time, spend more time with child, lose five pounds), then broke goals down into steps, utilizing

applications on mobile devices to record steps and set reminders on the iPod calendar application to complete GMT goal actions. At each subsequent home visit, a new two-month goal would be set by the veteran. A mobile application called "Mind Jogger" provides similar technology to past research providing "content free cues"[18,19] by randomly prompting (four times a day during waking hours) an "Executive Review," which involved veterans themselves asking the following *in vivo*: "What am I doing? What is my goal? What steps do I need to enact to achieve that goal? Do I need to refocus my concentration to enact these steps?" Veterans were asked to use a mobile application called "IQ Boost" daily to conduct the n-back task, in which they were presented a sequence of visual and/or auditory stimuli and then asked to identify whether the current stimulus was the same as the n^{th} prior stimulus. The n-back exercise lasted a few minutes and veterans were encouraged but not required to do multiple exercises at one sitting.

Veteran-family/friend dyads in the active control group received psychoeducation on TBI and used mobile devices to train visual memory. Clinical facilitators provided didactics and reviewed "Brain Health Training" psychoeducational materials about TBI and brain functioning, used previously in control groups in studies of GMT.[17,18] Additionally, veterans were asked to daily use a mobile application called "Unotan Memory" that involves matching colors, numbers, and images with visual-memory exercises. As in the experimental group, each exercise lasted a few minutes and veterans were encouraged but not required to do multiple exercises at one sitting.

Clinical facilitators were observed by other project staff using fidelity checklists until they achieved greater than 85% fidelity for six participant dyads (three in each study group). Afterward, facilitators could conduct sessions independently and then were observed randomly every three months to assure continued protocol fidelity.

Measures

Executive function was measured by the Delis-Kaplan Executive Function System (DKEFS) Color-Word inhibition task, a well-validated cognitive test measuring ability to inhibit automatic responses,[32] and the Barratt Impulsiveness Scale (BIS),[33] a self-report measure of attention, motor impulsivity, self-control, and cognitive instability.

Emotional regulation was measured by the Dimensions of Anger Reactions (DAR),[34] a self-report measure of anger disposition directed toward other people designed for and validated in combat veterans with PTSD, and the Head Injury Behavior Scale (HIBS),[35] a 20-item scale administered to family/friends to rate maladaptive interpersonal behaviors in individuals with head injuries (e.g., aggression, poor decision-making, irritability, lack of initiative).

Number of home visits completed (out of a possible 3) were measured. Application usage could not be directly captured by the mobile device and after use of an application, participants pressed a single button to log usage on an application called "Event Logger." Veterans and family/friends in the CALM group were asked whether veterans achieved GMT goals.

We administered the 17-item CAPS to measure frequency and intensity of PTSD symptoms.[31] Clinically meaningful change in PTSD symptoms is defined as a change in CAPS scores by 10 or more points.[36]

Statistical Analysis

Statistical analyses were conducted using SAS version 9.4. Descriptive analyses were conducted on characteristics of veterans and intervention process. To test hypotheses, difference scores for each outcome variable were tabulated by subtracting pretreatment scores from posttreatment scores. Then, difference scores were regressed

on treatment group, controlling for centered baseline levels of the outcome variable. Two sets of regression models were analyzed for each outcome. The first used listwise deletion (LD) and thus only included participants with baseline and posttreatment data. The second used an intent-to-treat (ITT) approach with last observations carried forward for participants with missing posttreatment data. Given PTSD was an inclusion criteria, we ran exploratory regression models of change in CAPS scores by treatment condition.

Results

Figure 1 presents the CONSORT diagram of participant flow through the study procedures. At randomization, the sample consisted of 112 Veteran-Family/Friend dyads. Social support included spouses/significant others (71%), friends (11%), parents (10%), siblings (2%), and "other" (6%). With respect to getting together with the family member/friend in the past year, 17% of veterans (n =19) reported at least once a day; another 23% (n = 25) at least once per week; 22% (n = 24) at least once per month; 27% (n = 30) less than once a month; and 11% (n = 12) not at all. With respect to talking on the telephone with the family member/friend in the past year, 32% of veterans (n =35) reported least at least once a day; another 35% (n = 39) at least once per week; 25% (n = 28) at least once per month; 6% (n = 7) less than once a month; and 2% (n = 2) not at all.

Of the 112 veteran/family-friend dyads (N=224 participants total), 89 returned at six months and provided posttreatment data (n = 41 in the CALM group and n = 48 in the Control group). Age, gender, CAPS, number of TBI, and racial status were not significantly associated with missing data. A greater percentage of CALM participants (28%) were missing posttreatment data than control participants (13%), $X^2(1) = 4.04$, p = .045. Background characteristics of veterans are reported in Table 1.

Across both study conditions, participants completed a mean of 2.73 out of 3 possible home visits (*SD* = 0.54). Visit rate did not vary by treatment condition, (*t*(87) = 0.77, *p* = .45). Not finishing all three home visits was mainly due to scheduling conflicts. Over the 6-month study, participants in CALM self-logged conducting an executive review after being cued a mean of 188.60 times (*SD* = 202.20) and using the n-back application a mean of 73.05 times (*SD* = 84.15). Participants in the control group self-logged using the visual-memory application a mean of 90.77 times (*SD* = 57.27). During the CALM intervention, 66% (n = 25) reported completing at least one GMT goal which generally involved physical, spiritual, financial, environmental, occupational, emotional/mental, intellectual, or social domains of wellness. Goal success in the CALM group was significantly associated with number of home visits conducted by clinical facilitators with veteran-family/friend dyads (*r* (36) = .44, *p* = .005).

Main hypotheses using regression analyses of treatment-related changes are reported in Table 2. No statistically significant changes by group on the DKEFS Color-Word inhibition task or the BIS were detected. However, significant treatment effects were observed for anger and TBI-related behavioral issues. Using an LD approach, veterans randomized to CALM reported an average 7.89-point decrease in anger towards others over six months on the DAR compared to 2.62 reduction in veterans in the control group (*B*= -5.27, *p* = .008) (see Figure 2). This difference on the DAR was significant (*B*= -3.35, *p* = .038) using an ITT approach. Family/friends reported that veterans randomized to CALM engaged in 2.39 fewer maladaptive interpersonal behaviors on the HIBS over six months on average, significantly greater than the reduction of 0.31 among veterans in the control (*B*= -2.08, *p* = .016). Group differences on the HIBS were significant using an ITT approach (*B*= -1.58, *p* = .021).

Pre- and posttreatment means and regression models of CAPS total, frequency, and intensity scores are listed in Table 3. Whereas the control group experienced a mean decrease in total symptom severity by 8.37 points (p = .002), the CALM group experienced a mean decrease of 15.20 points (p < .001). There was a trend for a treatment effect on total PTSD symptom severity when LD was used (B=-6.84, p = .084). Treatment effects were not significant in the ITT model and there were no significant effects on PTSD symptom intensity. However, in the PTSD symptom frequency model using the LD approach, treatment effects were significant (B=-4.09, p = .047), indicating veterans in the CALM group experienced greater decreases in symptom frequency than veterans in the control group.

Discussion

In the current study, veterans randomized to the CALM group did not show greater improvements in executive function but did demonstrate significantly larger decreases in anger towards others compared with veterans in the control group. Family/friends also reported significantly larger decreases in veterans randomized to the CALM group engaging in maladaptive behaviors such as aggression, irritability, and poor decision-making compared with those in the control group. Of CALM components, veterans' successful achievement of GMT goals was related to number of home visits by clinical facilitators. An unexpected result was that the CALM intervention was significantly associated with decreased PTSD symptoms.

Regarding executive function, we did not detect group differences in changes on the DKEFS Color-Word inhibition task or BIS. One possibility is that perhaps a different combination of training tasks would have yielded more favorable results on these particular outcomes. Another explanation is that only 12% of our sample demonstrated

functioning in the borderline or impaired range on the DKEFS color-word inhibition task at baseline, denoting a ceiling effect regarding ability to improve scores. Because most participants scored below the commonly used cut-off of 74 for impulsivity problems on the BIS,[33] our ability to assess reduction in impulsivity may likewise be due to floor effects. This has implications for clinical trials; namely, TBI alone may be insufficient as inclusion criteria for future treatment studies, which should instead specify cognitive and/or behavioral criteria.

Regarding emotional and behavioral regulation, current findings are consistent with research in cognitive rehabilitation of TBI showing that metacognitive strategies targeting self-awareness of beliefs, self-monitoring, and self-control are effective at improving social functioning.[13,18,19,23] That CALM was associated with greater reduction in anger toward others is noteworthy in treatment of veterans. In a nationally representative survey of U.S. Veterans,[37] 61.2% reported experiencing difficulties controlling anger while 23.9% reported experiencing aggressive urges over a two-year period. However, treatment of anger in veterans has lagged behind treatment of anxiety/fear and randomized clinical trials of anger treatments for veterans are rare.[7,38] CALM differs from most anger management interventions because it does not explicitly require identifying anger as a target, though it may encourage mindfulness and awareness of anger through random content free-cueing. Our results suggest integrating cognitive rehabilitation strategies into more targeted anger management programs for veterans may have potential for improving clinical and functional outcomes.

An unanticipated result was that over six months, total CAPS scores decreased by more than 15 points in veterans randomized to the CALM group, representing a clinically meaningful change in PTSD symptoms, defined as change in CAPS scores by 10 or more

points.[36] In hindsight, this might have been anticipated by the framework of psychosocial rehabilitation which posits that self-determination and self-direction are central tenets of recovery.[29] Further, given PTSD is a disorder characterized by feeling out of control of internal and external events,[39] it is not unreasonable to infer that providing tools and opportunities to practice strategies to achieve personally relevant goals could result in greater sense of control and reduction in PTSD symptomatology.

That the current study extends benefits of cognitive rehabilitation to veterans with TBI *and* PTSD is important because cognitive rehabilitation is seldom used in treating PTSD,[14] even though PTSD is linked to neuropsychological deficits.[3,4,40] The finding that CALM improved PTSD symptoms challenges the notion cognitive rehabilitation should be reserved for TBI only. The data imply PTSD and TBI should not necessarily be treated as distinct, non-overlapping conditions in veteran populations but instead be treated concurrently. The results support use of cognitive rehabilitation in conjunction with psychotherapeutic practices for veterans with PTSD.

Study limitations should be considered. The data may not generalize to all veterans with co-occurring TBI and PTSD because some veterans may not have a family member or friend they trust to participate in treatment. It is unknown whether CALM would yield similar effects for TBI-only or PTSD-only, though the fact that we observed improvement in an arguably more impaired population[2,4] speaks to potential for benefit. Similarly, future work could examine effects of CALM in civilian populations with TBI and/or PTSD.

Because mobile devices could not be programmed to measure application use, participants' self-logged entry served as a proxy. Although precise usage is unknown, participants in CALM automatically received content-free cues regardless of whether this

was logged in. Future studies should investigate optimal dosage, incorporate objective use measures, and track performance on the applications themselves. Given research on veterans with TBI and PTSD, we elected to study anger and impulsivity; however there are other domains of emotion regulation (e.g., coping skills) that warrant future study.

Although inclusion of family/friend informant data of TBI-related maladaptive behaviors is a strength of the study, the same informants were involved in administration of the interventions; ideally, future research would include collateral reports by individuals not involved in the intervention. Also, while we took steps to assure equivalence between study conditions regarding amount of time spent with clinical facilitators, it is possible the CALM group (e.g., involving goal setting) asked for somewhat more active effort on the part of participants than the control group (e.g., involving psychoeducation), which could be one reason more dyads dropped out of the former than the latter. Finally, longer term follow-up data would be useful to determine durability and longevity of effects of CALM.

On a practical level, the study identified that provision of a mobile device to facilitate cognitive rehabilitation was feasible. Its availability for use may have served as an incentive for initial participation in the study and encouraged ongoing participation throughout the study. The CALM intervention lends itself to the possibility of integrating it into treatment, involving social support, potentially using telemedicine and telerehabilitation to accomplish home visits, or developing it as an entirely self-directed application.

Still, that goal achievement was related to number of home visits challenges the notion of self-administered mobile technology and shows the contribution of clinician facilitation. Moreover, it will be important to study use of CALM in naturalistic settings

where individuals may use it on their smart phone devices which have other applications unrelated to cognitive rehabilitation. Additionally, attention should be given to understanding under which conditions social support facilitated improvement in CALM. More generally, the mechanism of change in CALM still needs investigation to determine whether benefits resulted from GMT goals, content-free cueing, the n-back, number of home visits, engagement of social support in veterans' recovery process, or an integrated face-to-face and technological treatment package. Future dismantling studies would help identify mechanisms of observed effects.

The results of this randomized clinical trial of the CALM intervention suggest that a mobile-based cognitive rehabilitation intervention is a viable approach to use with veterans and a family member or friend, and that it can result in improvements in emotional and behavioral regulation in veterans with co-occurring TBI and PTSD. Although this study is a preliminary step and findings need to be replicated, the results indicate that CALM holds promise for treating a growing population of veterans faced with what have become the two signature injuries of the wars in Iraq and Afghanistan.

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Table 1.

Baseline Participant Characteristics

	All (N = 112)	Control (n = 55)	CALM (n = 57)	p
Age	36.52 (8.42)	36.25 (8.30)	36.77 (8.60)	.75
Sex (female)	11 (10%)	5 (10%)	4 (10%)	.92
Racial minority status	53 (47%)	24 (50%)	14 (34%)	.13
TBI count	2.63 (1.24)	2.62 (1.25)	2.64 (1.24)	.92
TBI moderate/severe	64 (57%)	29 (53%)	35 (61%)	.35
CAPS total	75.63 (17.30)	75.98 (18.06)	75.30 (16.68)	.84
CW total	9.31 (3.51)	8.81 (3.68)	9.79 (3.32)	.15
BIS total	71.29 (12.75)	71.31 (12.42)	71.26 (13.17)	.98
DAR total	30.72 (15.55)	31.11 (15.54)	30.35 (15.69)	.80
HIBS total	8.72 (5.31)	9.80 (5.56)	7.68 (4.89)	.04

Note. Means/frequencies and standard deviations/percentages (in parentheses). CALM = Cognitive Applications for Life Management; TBI = traumatic brain injury; CAPS = Clinician Administered Posttraumatic Stress Disorder Scale; CW = DKEFS Color-Word inhibition task; BIS = Barratt Impulsivity Scale; DAR = Dimensions of Anger; HIBS = Head Injury Behavior Scale

Table 2.

Unadjusted Mean Changes and Modeled Unstardardized Treatment Effects on Changes in Main Outcome Variables

		Means (Standard Deviations)				Regression Coefficients (Standard Errors)		
		CALM		Control				
Outcome	Model	Pre	Post	Pre	Post	Intercept	Baseline level	Treatment[a]
Executive Function/Impulsivity								
CW	LD	9.80 (3.50)	10.25 (3.36)	8.69 (3.79)	9.91 (3.24)	0.76* (0.31)	-0.25** (0.06)	-0.12 (0.44)
	ITT	9.79 (3.32)	10.18 (3.23)	8.85 (3.68)	9.53 (3.48)	0.58* (0.25)	-0.18** (0.05)	-0.10 (0.35)
BIS	LD	69.34 (12.84)	67.29 (11.72)	71.04 (12.81)	68.98 (11.80)	-2.11* (0.98)	-0.21** (0.06)	-0.35 (1.44)
	ITT	71.26 (13.17)	69.79 (12.66)	71.31 (12.42)	69.69 (12.64)	-1.61† (0.83)	-0.14** (0.05)	0.14 (1.17)
Emotion/Behavior Regulation								
DAR	LD	30.68 (15.57)	22.80 (16.53)	30.74 (16.15)	28.13 (15.39)	-2.62* (1.31)	-0.17** (0.06)	-5.27** (1.93)
	ITT	30.35 (15.77)	24.82 (16.53)	31.13 (16.15)	28.85 (15.56)	-2.22† (1.14)	-0.14** (0.05)	-3.35* (1.60)
HIBS	LD	7.68 (4.88)	5.66 (4.67)	9.33 (5.21)	8.81 (5.23)	-0.31 (0.58)	-0.35** (0.09)	-2.08* (0.84)
	ITT	7.68 (4.89)	6.23 (4.83)	9.80 (5.56)	9.44 (5.77)	-0.12 (0.47)	-0.23** (0.06)	-1.58* (0.67)

Note. Negative effects reflect decreases in outcome measures from pre- to posttreatment; positive effects reflect increases. CALM = Cognitive Applications for Life Management; CW = DKEFS Color-Word inhibition task; BIS = Barratt Impulsivity Scale; DAR = Dimensions of Anger; HIBS = Head Injury Behavior Scale; LD = listwise deletion; ITT = intent to treat. †$p < .10$, *$p < .05$, **$p < .01$

[a] CALM vs. Control

Table 3.

Unadjusted Mean Changes and Modeled Unstandardized Treatment Effects on Changes in Exploratory PTSD Variables

CAPS Outcome	Model	Means (Standard Deviations)				Regression Coefficients (Standard Errors)		
		CALM		Control				
		Pre	Post	Pre	Post	Intercept	Baseline level	Treatment[a]
Total	LD	74.88 (16.85)	60.33 (25.14)	76.54 (18.07)	67.64 (24.05)	-8.34** (2.65)	-0.04 (0.11)	-6.84† (3.91)
	ITT	75.30 (16.68)	64.63 (23.92)	75.98 (18.06)	68.82 (23.55)	-7.15** (2.27)	-0.03 (0.09)	-3.53 (3.19)
Frequency	LD	38.98 (9.45)	29.80 (12.99)	39.71 (10.25)	34.02 (12.99)	-5.43** (1.37)	-0.08 (0.10)	-4.09* (2.02)
	ITT	39.42 (9.11)	32.75 (12.67)	39.64 (10.32)	35.00 (12.93)	-4.63** (1.21)	-0.05 (0.09)	-2.04 (1.69)
Intensity	LD	35.90 (8.06)	30.53 (13.15)	36.83 (8.39)	33.62 (11.75)	-2.92* (1.46)	-0.09 (0.13)	-2.77 (2.16)
	ITT	35.88 (8.30)	32.75 (12.67)	36.35 (8.33)	35.00 (12.93)	-2.51* (1.22)	-0.08 (0.10)	-1.51 (1.71)

Note. Negative effects reflect decreases in outcome measures from pre- to posttreatment; positive effects reflect increases. CAPS = Clinician Administered Posttraumatic Stress Disorder Scale; CALM = Cognitive Applications for Life Management; LD = listwise deletion; ITT = intent to treat. †$p < .10$, *$p < .05$, **$p < .01$

[a] CALM vs. Control

Figure 1.

Study Procedures, Screening, and Participant Enrollment

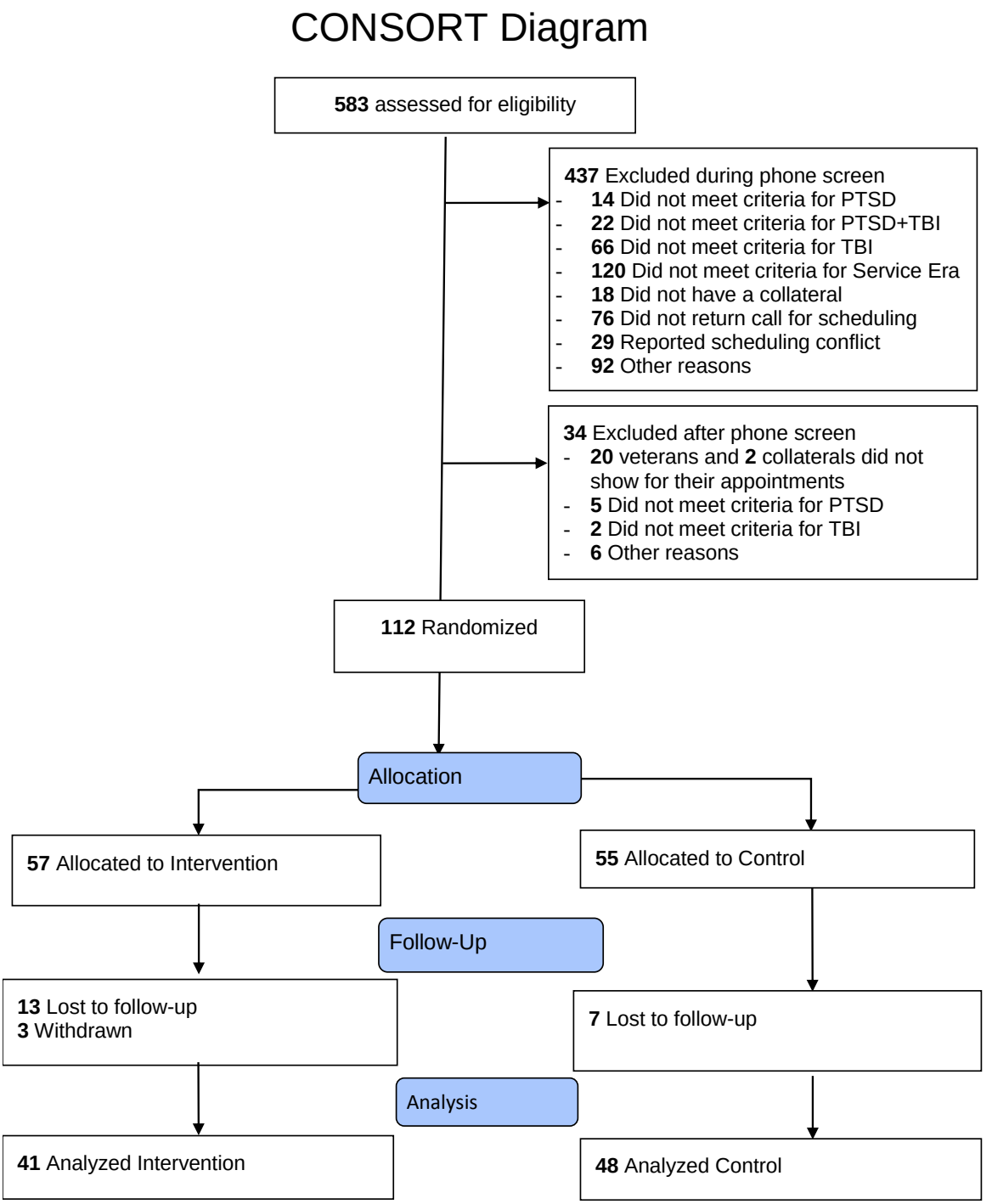
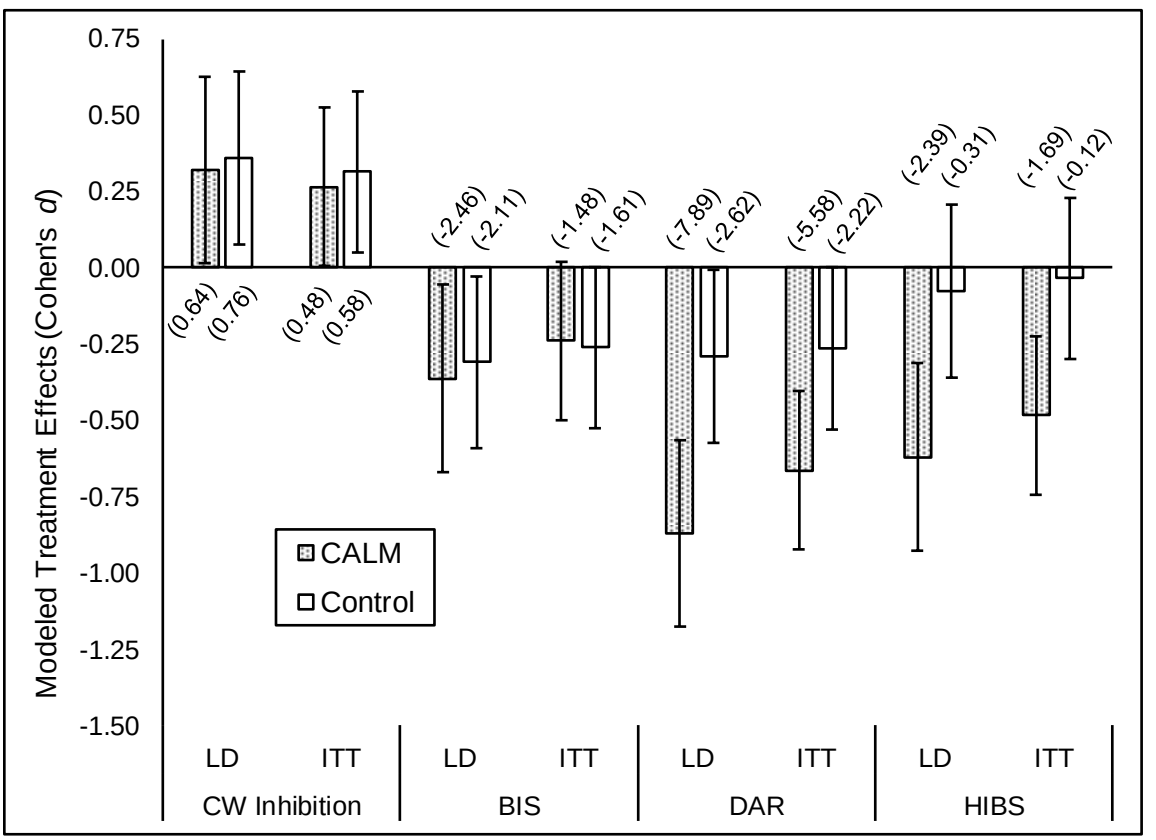


Figure 2.

Modeled treatment-associated changes in main outcome variables.



Note. Negative scores reflect reductions from baseline, positive scores increases. Standardized units (Cohen's *d*) are depicted with raw modeled change scores reported in parentheses. Error bars represent 95% confidence intervals. CALM = Cognitive Applications for Life Management; CW = DKEFS Color-Word inhibition task; BIS = Barratt Impulsivity Scale; DAR = Dimensions of Anger; HIBS = Head Injury Behavior Scale; LD = listwise deletion; ITT = intent to treat.